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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/544,773	04/07/2000	Antonio Arevalo Reyes	3239-104P	1014

2292 7590 10/24/2002

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EXAMINER

MYERS, CARLA J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 10/24/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/544,773

Applicant(s)

REYES ET AL.

Examiner

Carla Myers

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1634

1. This action is in response to the amendment of Paper No. 13, filed April 15, 2002. Applicants' arguments presented in the response of Paper No. 13 have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. This action is made final.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-3, 6-13, 16-18 and 21-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Newton et al (U.S. Patent No. 5,525,494).

Newton (see, for example, col. 2-3) teaches a method for amplifying a target nucleic acid wherein the method comprises contacting a sample nucleic acid, together or sequentially, with a first primer comprising a target binding region and a polynucleotide tail and with an amplification primer comprising a target binding region and a polynucleotide tail, in the presence of a polymerization agent under conditions in which the first primer and amplification primer anneal to the target nucleic acid and wherein the first primer and the amplification primer are extended to generate an amplification product. The first primer and the amplification primer each contain a polymerization blocking moiety positioned between the target binding region and the tail. In particular, "the first primer may be subjected to primer extension whereby a first

Art Unit: 1634

primer extension product is synthesized based on the target nucleotide sequence as template, and after denaturation of the first primer extension product from its template and hybridization of the amplification primer to the desired portion of the first primer extension product, primer extension may be effected to form an amplification primer extension product, the presence of the first primer in the first primer extension product being effective to inhibit formation of a sequence complementary to the polynucleotide tail in the amplification primer extension product” (see col. 2, lines 36-48). Similarly, the presence of the amplification primer in the amplification primer extension product is effective to inhibit the formation of a sequence complementary to the polynucleotide tail of the primer extension product. Accordingly, Newton teaches amplification methods utilizing a first and second primer comprising a “non-replicable element”. Newton teaches that the target sequence may be RNA or DNA (col. 6, lines 20-24) and teaches that the agent for polymerization may be any suitable DNA polymerase or reverse transcriptase (see col. 6, lines 44-51). The method of annealing primers to the template and separating the primer extension products from their templates may be repeated as many times as necessary to obtain the desired level of sequence amplification (col. 2). Thereby, Newton teaches that the amplification method is one for synthesizing cDNA from an RNA template and for further amplifying cDNA amplification products. Newton (col. 9) teaches that the polymerization blocking moiety may be a deoxy ribofuranosyl naphthalene or ribofuranosyl naphthalene moiety, which are considered to be derivatives of a deoxyribonucleotide and derivatives of a ribonucleotide. The primers of Newton are considered to contain “cleavable elements” because

Art Unit: 1634

all nucleotides present in the primers can be cleaved by some type of cleaving agent, such as a nuclease, ribonuclease, etc.

RESPONSE TO ARGUMENTS:

In the response of Paper No. 13, Applicants traverse this rejection on the following grounds. Applicants argue that Newton does not disclose or suggest primers containing non-replicable elements or cleavable elements to halt primer extension products. This argument is not convincing because it is directed to limitations not recited in the claims because the claims do not specifically require a method which "halts primer extension products." Applicants state that Newton includes the blocking agent in the template, rather than in the primer. This argument is not persuasive because Newton does in fact teach including the "blocking agent" in the primer. At column 2, Newton states that "(t)he first primer may if desired comprise the target binding nucleotide and the polynucleotide tail with a nucleotide polymerisation blocking moiety there between." Further, at column 3, Newton states that "(i)f desired the amplification primer may, in addition to the first primer, comprise:....As stated in relation to the first primer, a nucleotide polymerisation blocking moiety may if desired be positioned between the target binding nucleotide moiety and the polynucleotide tail." Accordingly, Newton teaches incorporating a blocking moiety into the first primer and the amplification primer (second primer). Applicants further assert that "(n)othing in Newton suggests stopping primer extension after the generation of only second generation primer extension products, which is a feature asserted in the instant claims." However, again, the claims do not require this particular

Art Unit: 1634

limitation and the steps recited in the claims do not specifically result in a method in which primer extension is stopped after the generation of only second generation primer extension products.

3. THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:

Claim 2, 3 and 6-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 3 and 6-15 are indefinite over the recitation of "said first and said complement cDNA strands" because this phrase lacks proper antecedent basis. While the claims previously refer to a "first strand cDNA product" and a "complement of said first cDNA strand", the claims do not previously refer to a "first and said complement cDNA strands." The claims should be amended to consistently refer to either the "cDNA strand" or the "first strand cDNA."

Claims 2, 3 and 6-15 are indefinite because it is unclear as to whether the primers defined in these claims at step b) are the same as or different from the primers set forth in claim 1, from which claims 2, 3 and 6-15 depend.

Claims 2 and 6-15 are indefinite over the recitation of "primers of claim 2" because it is improper for a dependent claim to refer back to itself.

Art Unit: 1634

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

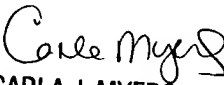
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

October 24, 2002


CARLA J. MYERS
PRIMARY EXAMINER